The Clinical Investigator: Responsibilities in Medical Device Clinical Trials

Presented by Catherine Parker, RN

Consumer Safety Officer
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and Radiological Health

Objectives

- Define a medical device clinical investigator
- Explain the general and specific responsibilities of investigators
- Describe records and reporting requirements of investigators

Presentation Topics

- General responsibilities
- Specific responsibilities
- Records
- Inspections
- Reports

What is a Clinical Investigator (CI)?

- An individual who actually conducts a clinical investigation, under whose immediate direction the test article is administered, dispensed, or used.

General Responsibilities

21 C.F.R. 812.100

- Follow the investigator agreement, the investigational plan, and applicable regulations
- Protect the rights, safety, and welfare of subjects
- Control devices under study
- Obtain informed consent

Specific Responsibilities

21 C.F.R. 812.110

- Obtain IRB and FDA approval
- Follow investigator agreement, investigational plan, and conditions of approval imposed by IRB or FDA
- Supervise device use
- Disclose financial interests
- Dispose of device

Disqualification

21 C.F.R. 812.119

- An investigator's repeated or deliberate failure to comply with these requirements may result in disqualification from receiving investigational devices

Investigator Records

21 C.F.R. 812.140(a)

- All correspondence with another investigator, Institutional Review Board (IRB), sponsor, monitor, or FDA

Device Records

21 C.F.R. 812.140(a)

- Records of receipt, use, and disposition of device including:
  - Type and quantity of the devices, dates of receipt, and batch number or code mark
  - Name of all persons who received, used, or disposed of each device
  - Why and how many devices have been returned, repaired, or other wise disposed of

Case Histories

21 C.F.R. 812.140(a)

- Exposure to the device
- CRFs and supporting data
  - Informed consent documents
  - Adverse device effects
  - Any relevant observations

Protocols

21 C.F.R. 812.140(a)

- All IRB approved amendments
  - Including approvals
- Documentation of protocol deviations and IRB and sponsor approvals

Record Retention

21 C.F.R. 812.140(d)

- Two years after study termination or completion
- Two years after records are no longer required to support marketing application

Records Custody

21 C.F.R. 812.140(e)

- Withdraw responsibility to maintain records
- Transfer custody to any other person who will accept responsibility
- Notice of transfer to FDA not later than 10 working days

Documentation

If it is not documented, it never happened!

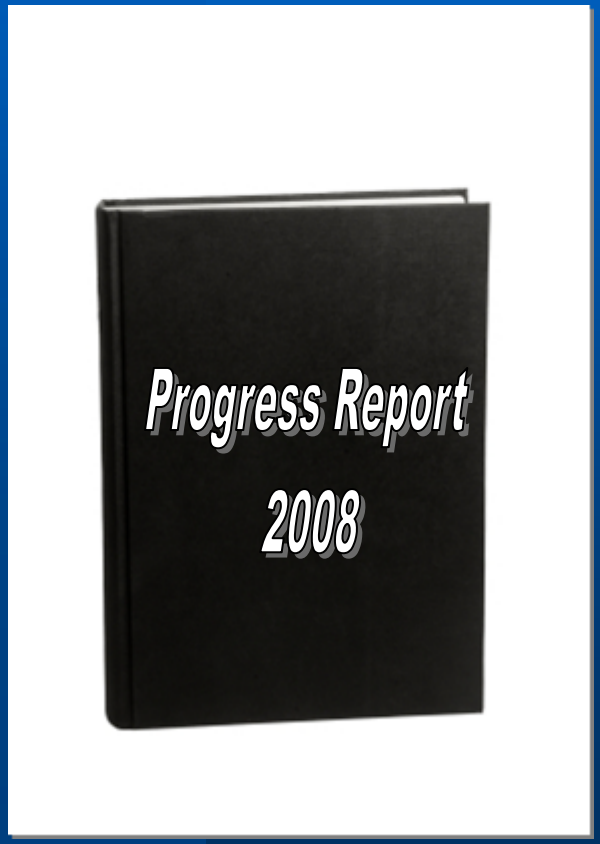
FDA Inspections

21 C.F.R. 812.145

- Occur at reasonable times and in a reasonable manner
- Permit records to be inspected and copied

Investigator Reports

21 C.F.R. 812.150



- Unanticipated Adverse Device Effects
- Withdrawal of IRB approval
- Progress reports
- Deviations from the investigational plan
- Informed consent
- Final report
- Other

Adverse Effect

- Any adverse medical occurrence that may or may not be related to the investigational device

All adverse effects should be documented

Unanticipated Adverse Device Effect

21 C.F.R. 812.3(s)

- Any serious adverse effect that is possibly caused by or related to the investigational device:
  - Not previously identified in nature, severity, or degree, or
  - Any other unanticipated serious problem associated with a device

Investigator Responsibilities- AEs and UADEs

- Report Unanticipated AEs to the sponsor and IRB within 10 working days
- Maintain records of all AEs (anticipated or unanticipated)
- Follow the sponsor's requirements for reporting and recording of AEs and UADEs

Study Deviations

21 C.F.R. 812.140(a)

- Document dates and reasons for any deviations from the study protocol
- Emergency deviations must be reported to the sponsor and IRB within 5 days
- Obtain prior approval from the sponsor, IRB, and FDA for changes or deviations from the investigational plan

Summary

- A clinical investigator conducts a clinical investigation.
- CI responsibilities are designed to:
  - Protect human subjects
  - Promote the collection of quality data